# PCT/IB2004/04405

Internamnal Application No

# INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, Sequence Search, BIOSIS, PAJ, WPI Data, EMBASE, CHEM ABS Data, LIFESCIENCES, SCISEARCH

C. DOCUMENTS CONSIDERED TO BE RELEVANT  Relevant to claim		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	
X .	"Affymetrix GeneChip Human Genome U95 Set HG-U95A" GENBANK GEO, 11 March 2002 (2002-03-11), XP002293987 see affymetrix probe-set 33799_at, 31625_at, 41680_at, 1239_s_at; 1240_at and 32818_at	1-7,9-14
L	DATABASE EMBL 'Online!  3 February 2004 (2004-02-03), "Sequence  3748 from Patent W002068579."  XP002321904  retrieved from EBI accession no.  EM_PAT:CQ717814  Database accession no. CQ717814  L document cited to provide information on the relevant sequence disclosed in W0-A-02068579.  the whole document	

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
Special categories of cited documents:      A' document defining the general state of the art which is not considered to be of parlicular relevance      E' earlier document but published on or after the International filling date      C' document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)      O' document referring to an oral disclosure, use, exhibition or other means      P' document published prior to the international filling date but later than the priority date claimed  Date of the actual completion of the international search	"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory, underlying the trivention  "X" document of particular relevance; the claimed Invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken atone  "Y" document of particular relevance; the claimed Invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "&" document member of the same patent family  Date of mailing of the international search report
11 May 2005	08/06/2005
Name and mailing address of the ISA  European Patent Office, P.B. 5818 Patentlaan 2  NL – 2280 HV Rijsvrijk  Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  Fax: (+31-70) 340-3016	Authorized officer  Schmitt, C

ズナン	7 7 7
2	
-	

	tion) DOCUMENTS CONSIDERED TO BE RELEVANT  Citation of document, with Indication, where appropriate, of the relevant passages	Relevant to claim No.
ategory °	Calation of document, with indication, where depropriate	
(	-& WO 02/068579 A (PE CORPORATION) 6 September 2002 (2002-09-06) whole document, in particular: claims 1,4,5,8,9,12,13,16 page 12, line 18 - line 34 page 15, line 23 - line 31 page 20, line 5 - page 24, line 7	1-7,9-16
-	DATABASE EMBL 'Online! 3 February 2004 (2004-02-03), "Sequence 15057 from Patent W002068579." XP002321905 retrieved from EBI accession no.	
	EM_PAT:CQ729123 Database accession no. CQ729123 L document cited to provide information on the relevant sequence disclosed in WO-A-02068579.	
X	the whole document  -& WO 02/068579 A (PE CORPORATION) 6 September 2002 (2002-09-06) whole document, in particular: claims 1,4,5,8,9,12,13,16 page 12, line 18 - line 34 page 15, line 23 - line 31 page 20, line 5 - page 24, line 7	1-7,9-16
	DATABASE EMBL 'Online!  3 February 2004 (2004-02-03), "Sequence 10220 from Patent W002068579."  XP002321906 retrieved from EBI accession no. EM_PAT:CQ724286 Database accession no. CQ724286 L document cited to provide information on the relevant sequence disclosed in WO-A-02068579.	
X	the whole document  -& WO 02/068579 A (PE CORPORATION) 6 September 2002 (2002-09-06) whole document, in particular: claims 1,4,5,8,9,12,13,16 page 12, line 18 - line 34 page 15, line 23 - line 31 page 20, line 5 - page 24, line 7	1-7,9-16
L	DATABASE EMBL 'Online! 3 February 2004 (2004-02-03), "Sequence 4515 from Patent W002068579." XP002321907 retrieved from EBI accession no. EM_PAT:CQ718581 Database accession no. CQ718581 L document cited to provide information on the relevant sequence disclosed in W0-A-02068579.	

# INTERNATIONAL SEARCH REPORT

internania Application No PĆT/IB2004/04405

	ation) DOCUMENTS CONSIDERED TO BE RELEVANT  Citation of document, with Indication, where appropriate, of the relevant passages	Relevant to claim No.
ategory °	Citation of document, with indication, where appropriate	
(	-& WO 02/068579 A (PE CORPORATION) 6 September 2002 (2002-09-06) whole document, in particular: claims 1,4,5,8,9,12,13,16 page 12, line 18 - line 34 page 15, line 23 - line 31 page 20, line 5 - page 24, line 7	1-7,9-16
	JANSEN M ET AL: "Molecular classification of tamoxifen-responsive and -resistant breast carcinomas by gene expression profiling."  BREAST CANCER RESEARCH AND TREATMENT, vol. 82, no. Supplement 1, November 2003 (2003-11), page S14, XP002321901  & 26TH ANNUAL SAN ANTONIO BREAST CANCER SYMPOSIUM; SAN ANTONIO, TX, USA; DECEMBER 03-06, 2003  ISSN: 0167-6806 the whole document	
X	PAIK S ET AL: "MULTI-GENE RT-PCR ASSAY FOR PREDICTING RECURRENCE IN NODE NEGATIVE BREAST CANCER PATIENTS-NSABP STUDIES B-20 AND B-14" BREAST CANCER RESEARCH AND TREATMENT, NIJHOFF, BOSTON, US, vol. 82, no. SUPPL 1, 3 December 2003 (2003-12-03), pages S10-S11,ABSTRN, XP001202622 ISSN: 0167-6806 cited in the application the whole document	17,18
A	STREEKUMAR A ET AL: "USING PROTEIN MICROARRAYS TO STUDY CANCER" BIOTECHNIQUES, EATON PUBLISHING, NATICK, US, no. SUPPL, December 2002 (2002-12), pages 46-53, XP009018820 ISSN: 0736-6205 the whole document	15,16
A	LOS GERRIT ET AL: "Using mRNA expression profiling to determine anticancer drug efficacy" CYTOMETRY, vol. 47, no. 1, 1 January 2002 (2002-01-01), pages 66-71, XP002321902 ISSN: 0196-4763 page 69, column 1, paragraph 2 - column 2, paragraph 1	17,18

### INTERNATIONAL SEARCH REPORT

Internation No
| PCT/IB2004/04405

	•	PCT/IB200	)4/04405	
C.(Continua	C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT			
Category •	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.	
P,A	DOWSETT MITCH: "Biomarker investigations from the ATAC trial: the role of TAO1." BREAST CANCER RESEARCH AND TREATMENT. 2004, vol. 87 Suppl 1, 2004, pages S11-S18, XP002321903 ISSN: 0167-6806			
P,A	MA X-J ET AL: "A two-gene expression ratio predicts clinical outcome in breast cancer patients treated with tamoxifen" CANCER CELL, XX, US, vol. 5, no. 6, June 2004 (2004–06), pages 607–616, XP002317299 ISSN: 1535–6108	·		
T	JANSEN MAURICE P H M ET AL: "Molecular classification of tamoxifen-resistant breast carcinomas by gene expression profiling."  JOURNAL OF CLINICAL ONCOLOGY: OFFICIAL JOURNAL OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY. 1 FEB 2005, vol. 23, no. 4, 1 February 2005 (2005-02-01), pages 732-740, XP009045184		1-7,9-18	
	ISSN: 0732-183X 			
	•			

### FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 8

Claim 8, which is dependent on independent claim 1 relate to a set of marker genes comprising the 44 genes of the 44-gene signature listed in Table 1.

However, no gene is identified in Table 1. In view of the description (e.g. page 3 or page 6, section "44-gene signature"), which indicates that the listing of genes of the 44 gene predictive signature is found in Figure 2, and the fact that Figure 2A and Figure 2B are listing the same 44 genes; claim 8 is interpreted as relating to a set of marker genes comprising the 44 genes of the 44-gene signature listed in Figure 2B.

However, it appears that, at least one of the 44 genes of the 44-gene signature listed in Figure 2B is not clearly defined (Article 6 PCT). In particular, one of the 44 genes defining the 44-gene signature listed in Figure 2B is only identified by its unigene accession number Hs.437986. Said unigene accession number is however deleted from the database. The gene with unigene accession number Hs.437986 is therefore not clearly identified.

Thus, in the absence of a clear and unambiguous definition of all of the 44 genes of the 44-gene signature listed in Figure 2B, no search is performed for claim 8.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

# REST AVAILABLE COF!

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2004/04405

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This international Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
Claims Nos.:     because they relate to subject matter not required to be searched by this Authority, namely:
<del>-</del>
2. X Claims Nos.: 8 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  see FURTHER INFORMATION sheet PCT/ISA/210
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
·
As all required additional search fees were timely paid by the applicant, this international Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
Concernative this International Search Report is
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest  The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

### INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No PCT/IB2004/04405

Patent document clted in search report	Publication date .	on Patent family member(s)		Publication date
WO 02068579 A	06-09-2002		)2068579 A2	06-09-2002